



GUARD SYMPOSIUM

guardsymposium2023
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6-7 JULIO 2023

GU-Alliance for Research
and Development

SAKK Urogenital Project Group

Mohamed Shelan

Assistant Professor of Radiation Oncology
Bern University Hospital



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Disclosures



Institutional receipt of grants / research supports

Debio Pharm



Receipt of honoraria or consultation fees

Debio Pharm

Astellas

Janssen

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Introducing SAKK



Non-profit organization
with over 50 years of
history

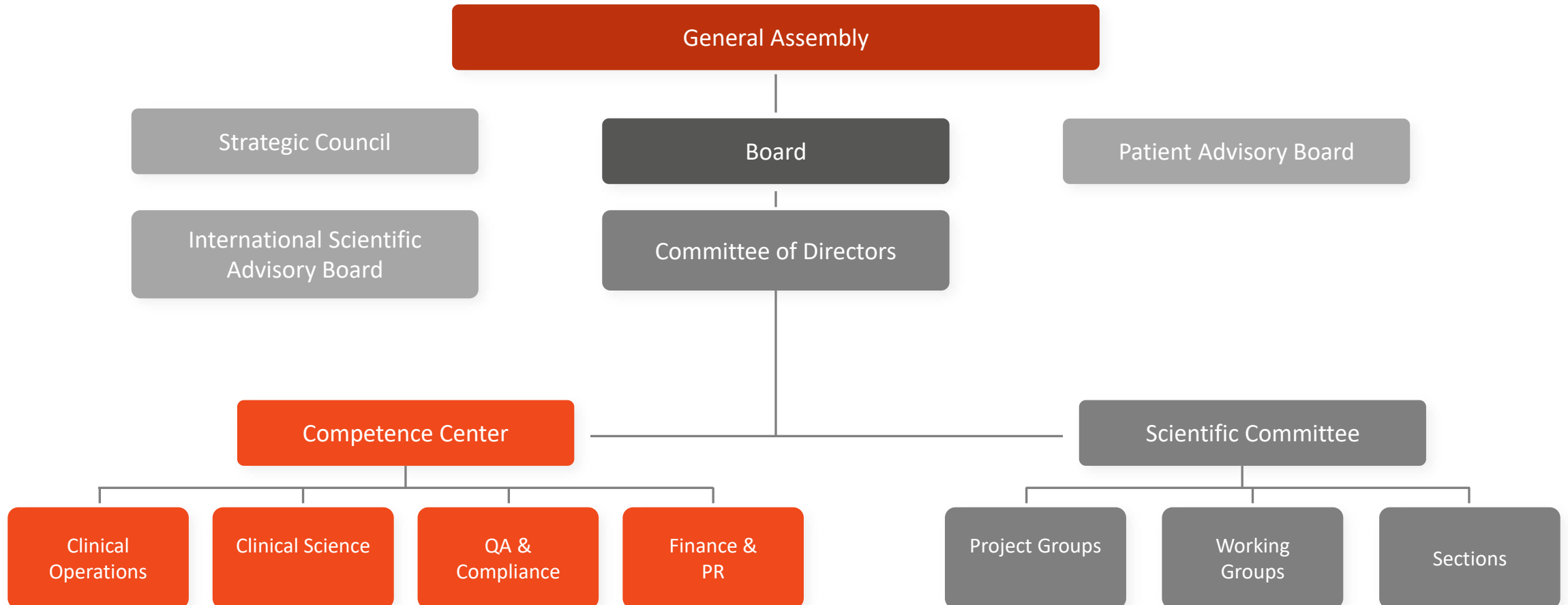


Decentralized academic
research institute with
22 major Swiss hospitals



Performance mandate
from the Swiss
government since 1974

SAKK Organization Chart



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Competence Center of SAKK



Located in Bern



80 Employees

Support trial
protocols
development

Organize
Infrastructure for
the groups

Support in funding acquisition



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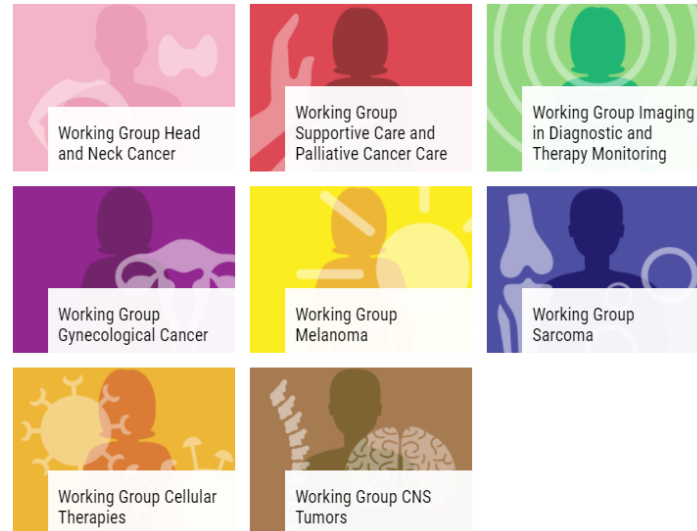
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Scientific Committee

Project Groups



Working Groups



Sections



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Research Objectives



Main Objectives

- ✓ Increase cure rate, life expectancy and quality of life of patients
- ✓ Primary prevention of tumor diseases

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Research Objectives



Secondary Objectives

- ✓ Promoting multi-disciplinarity
- ✓ Conducting therapy-optimizing trials with long-term monitoring
- ✓ Cooperation with international academic research groups
- ✓ Access to new drugs, medical devices and methods

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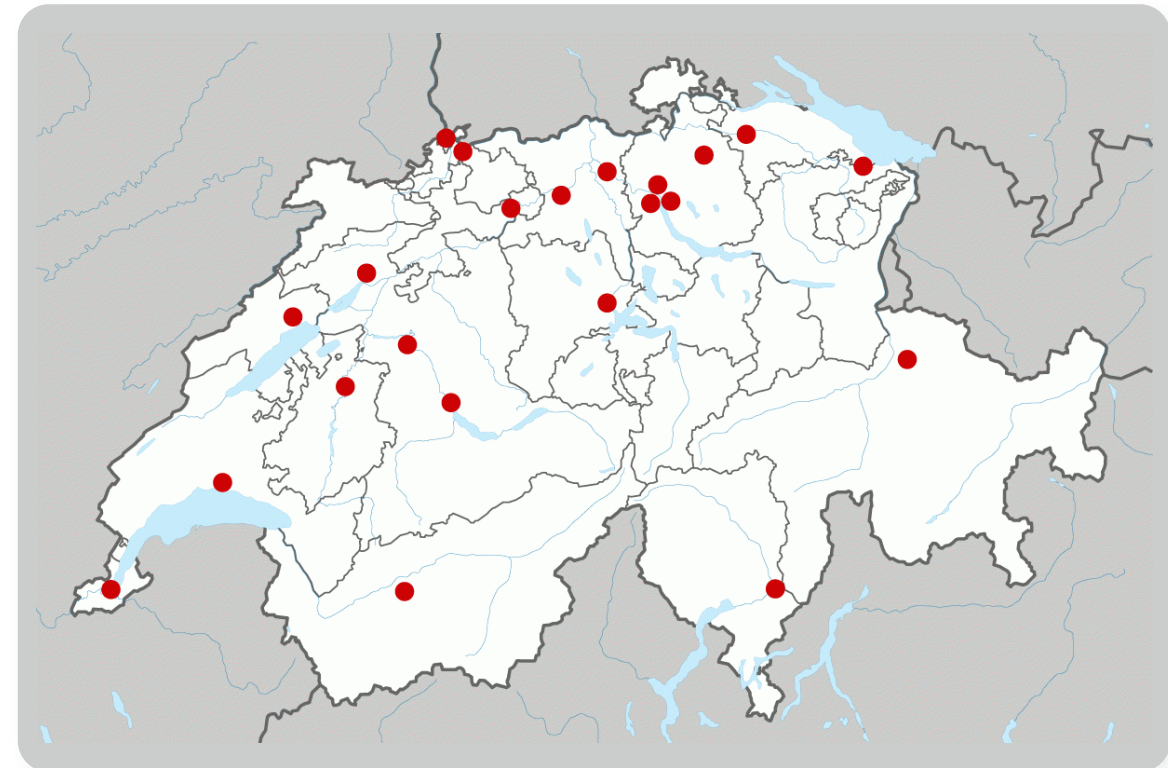
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- Active members: 103
- Institutions with voting rights: 22

- ✓ Hôpitaux Universitaires Genève
- ✓ Hôpital Fribourgeois
- ✓ Réseau Hospitalier Neuchâtelois
Hôpital du Valais
- ✓ Solothurner Spitäler
- ✓ Universitätsspital Basel
- ✓ Kantonsspital Aarau
- ✓ Luzerner Kantonsspital
- ✓ Hirslanden
- ✓ Kantonsspital Winterthur
- ✓ Istituto Oncologico della
- ✓ Kantonsspital St. Gallen
- ✓ Centre Hospitalier Universitaire Vaudois
- ✓ Spitalzentrum Biel
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President



Aurelius Omlin, Medical
Oncologist (Onkozentrum Zürich)



Vice president



Alexandros Papachristofilou,
Radiation Oncologist (USB)



Martina
Schneider

SAKK Senior Clinical Project
Developer



Stefanie Hayoz

SAKK Head of Statistics



Core Team



Christian
Fankhauser

Urologist



Petros
Tsantoulis

Medical Oncologist



Mohamed
Shelan

Radiation Oncologist

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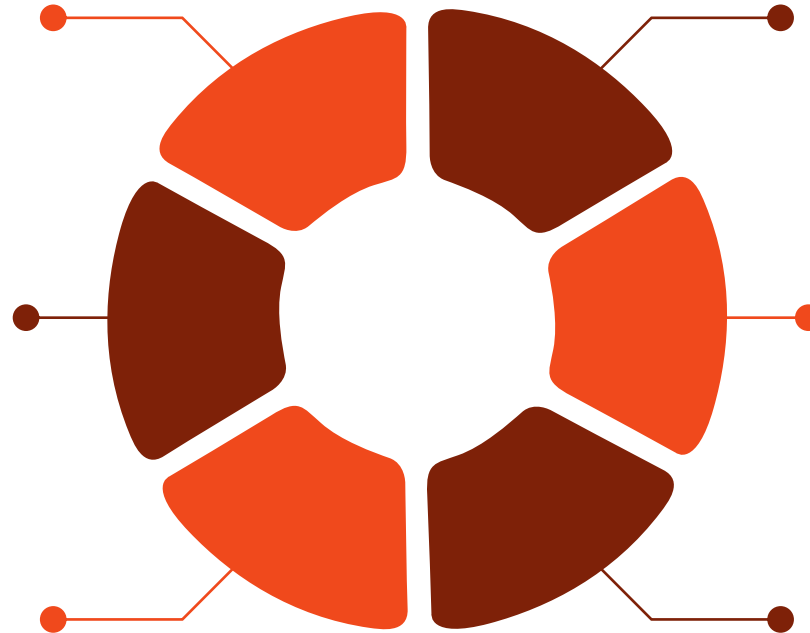
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Objectives

Keep a motivated and active
Core Team

Exchange with pharma
companies to define
collaboration fields

Increase number of open
trials



Develop and Implement
research strategy

Continue to increase
interdisciplinarity (Medical
Oncologist, Radiation Oncologists,
Urologists, Nuclear Medicine
Experts...)

Successful initiation and timely
completion of clinical trials

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Trials Portfolio



Important publications from the GU Group

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Trial	2020	2021	2022	2023	Total
PEACE-4	1				1
SAKK 01/18	15	44	32	25	116
SAKK 06/19			5	On hold	5
SAKK 07/17	25	5			30
SAKK 08/14	22	3			25
SAKK 08/15	32				32
SAKK 08/16	36				36
SAKK 09/18	43				43
SAKK 63/12	49				49
SAKK 96/12	89	8	36	13	146
SCORED: SAKK 80/19	19	33			52
SCORED: SAKK 80/20	58				58
Total	389	93	73	38	593

2020:
12 open trials

2023:
3 open trials!!



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Treatment of patients with bone metastases using Xgeva®

SAKK 96/12

Coordinating investigator



Prof. Dr. med. Roger von Moos
Kantonsspital Graubünden
+41 81 256 66 47

Bone metastases – the spread of cancer to the bones – are a frequent complication in patients with advanced cancer, and new cases are diagnosed in Switzerland in more than 5000 people a year. Since it was granted marketing approval in December 2011, Xgeva® has been increasingly used for the treatment of patients with bone metastases.

Reduced-intensity radio-chemotherapy in patients with testicular cancer

SAKK 01/18

Coordinating investigator



Dr. med. Alexandros Papachristofilou

Universitätsspital Basel

+41 61 265 49 46

Every year around 450 men in Switzerland develop testicular cancer, which is the most common type of cancer in men aged between 18 and 35. Early-stage seminomas usually respond well to treatment.

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SAKK UG PG Publications

Date online	Type	Trial	Title	Journal	Impact factor
01/08/2019	Secondary	SAKK 08/14	Analysis of AR/ARV7 Expression in Isolated Circulating Tumor Cells of Patients with Metastatic Castration-Resistant Prostate Cancer (SAKK 08/14 IMPROVE Trial).	CANCERS	5.326
22/08/2019	Intergroup	STAMPEDE	Abiraterone in "High-" and "Low-risk" Metastatic Hormone-sensitive Prostate Cancer	EUR UROL	13.938
21/04/2020	Primary	SAKK 06/14	Results of the phase I open label clinical trial SAKK 06/14 assessing safety of intravesical instillation of VPM1002BC, a recombinant mycobacterium Bacillus Calmette Guérin (BCG), in patients with non-muscle invasive bladder cancer and previous failure of conventional BCG therapy	ONCOIMMUNOLOGY	5.333
14/06/2021	Primary	SAKK 09/10	Dose-intensified versus conventional dose salvage radiotherapy for biochemically recurrent prostate cancer after prostatectomy: the SAKK 09/10 randomised phase 3 trial	EUR UROL	13.938
23/12/2021	Intergroup	STAMPEDE	Abiraterone acetate and prednisolone with or without enzalutamide for high-risk non-metastatic prostate cancer: a meta-analysis of primary results from two randomised controlled phase 3 trials of the STAMPEDE platform protocol	LANCET	79.321
02/01/2022	Secondary	SAKK 09/10	Adherence to contouring and treatment planning requirements within a multicentric trial -results of the quality assurance of the SAKK 09/10 trial	INT J RADIAT ONCOL BIOL PHYS	4.495
07/01/2022	Primary	SAKK 06/14	Results of a phase II single arm clinical trial assessing efficacy, safety and tolerability of the recombinant Bacillus Calmette Guérin (rBCG) VPM1002BC in patients with high-grade non muscle-invasive bladder cancer recurrence after BCG induction with or without BCG maintenance therapy – SAKK 06/14	EUR UROL ONCOL	7.479
16/05/2022	Intergroup	STAMPEDE	Abiraterone acetate plus prednisolone for metastatic patients starting hormone therapy: 5-year follow-up results from the STAMPEDE randomised trial (NCT00268476)	INT J CANCER	7.316
28/05/2022	Secondary	SAKK 09/10	Validation of the Decipher Genomic Classifier in SAKK 09/10: A Phase 3 Randomized Trial of Dose-escalated Salvage Radiotherapy after Radical Prostatectomy	ANN ONCOL	7.04
25/07/2022	Intergroup	STAMPEDE	Docetaxel for Nonmetastatic Prostate Cancer: Long-Term Survival Outcomes in the STAMPEDE Randomized Controlled Trial	JNCI CANCER SPECTR	.
10/10/2022	Primary	SAKK 01/10	Single-dose carboplatin followed by involved-node radiotherapy for stage IIA/B seminoma: SAKK 01/10	LANCET ONCOL	54.433

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EUROPEAN UROLOGY 80 (2021) 306–315

available at www.sciencedirect.com
journal homepage: www.europeanurology.com



European Association of Urology



Platinum Priority – Prostate Cancer

Editorial by Sophia C. Kamran on pp. 316–318 of this issue

Dose-intensified Versus Conventional-dose Salvage Radiotherapy for Biochemically Recurrent Prostate Cancer After Prostatectomy: The SAKK 09/10 Randomized Phase 3 Trial

Pirus Ghadjar^{a,}, Stefanie Hayoz^b, Jürg Bernhard^{c,d}, Daniel R. Zwahlen^{e,†}, Tobias Hölscher^f,
Philipp Gut^{g,†}, Bülent Polat^h, Guido Hildebrandtⁱ, Arndt-Christian Müller^j, Ludwig Plasswilm^{a,k},
Alexandros Papachristofilou^l, Corinne Schär^b, Marcin Sumila^m, Kathrin Zaugg^{a,n},
Matthias Guckenberger^o, Piet Ost^p, Christiane Reuter^q, Davide G. Bosetti^r, Kaouthar Khanfir^s,
Silvia Gomez^t, Peter Wust^u, George N. Thalmann^v, Daniel M. Aebersold^a, on behalf of the Swiss
Group for Clinical Cancer Research (SAKK)[§]*

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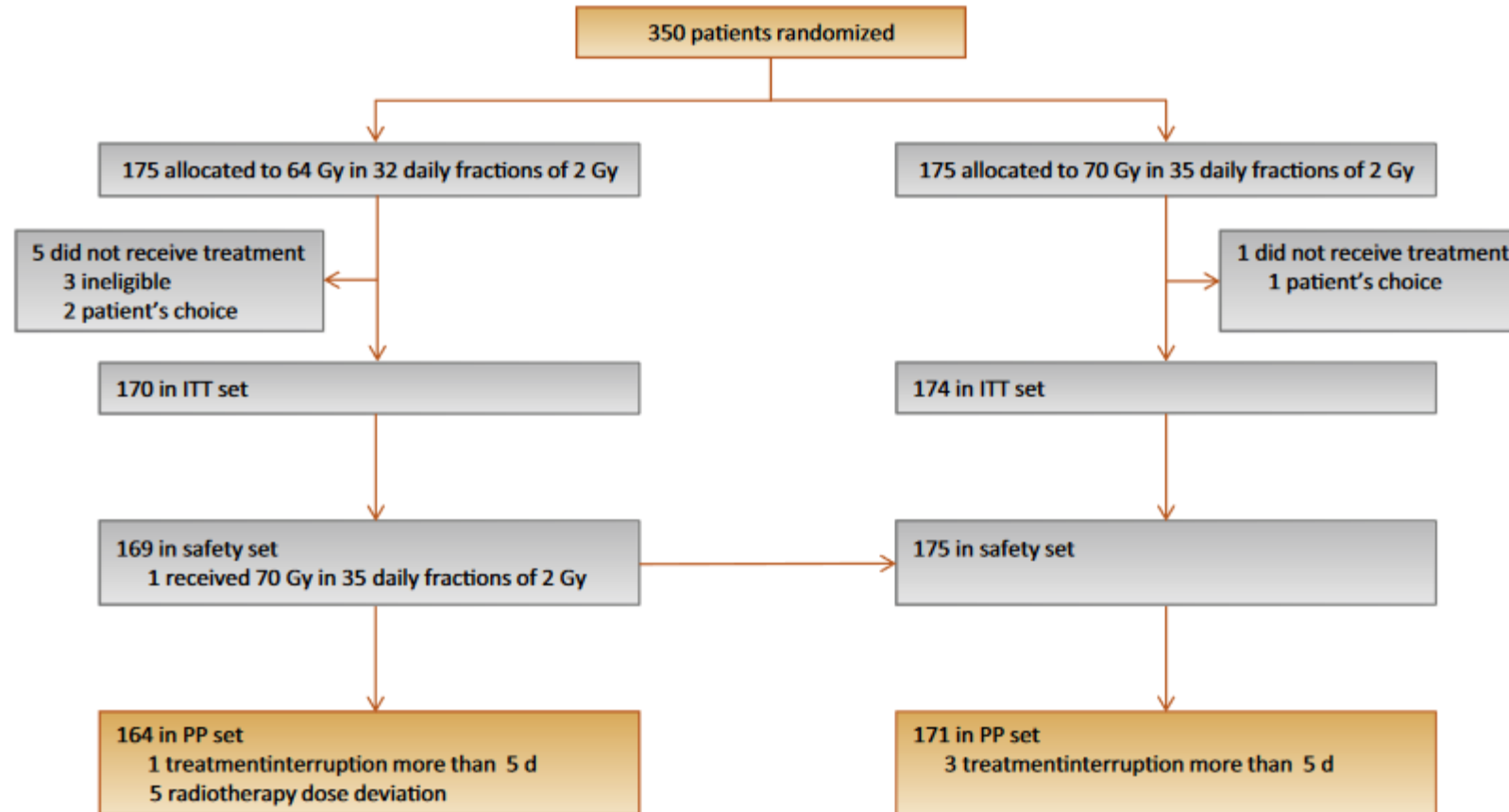


Fig. 1 – CONSORT diagram for the SAKK 09/10 randomized trial. ITT=intention to treat; PP=per protocol.

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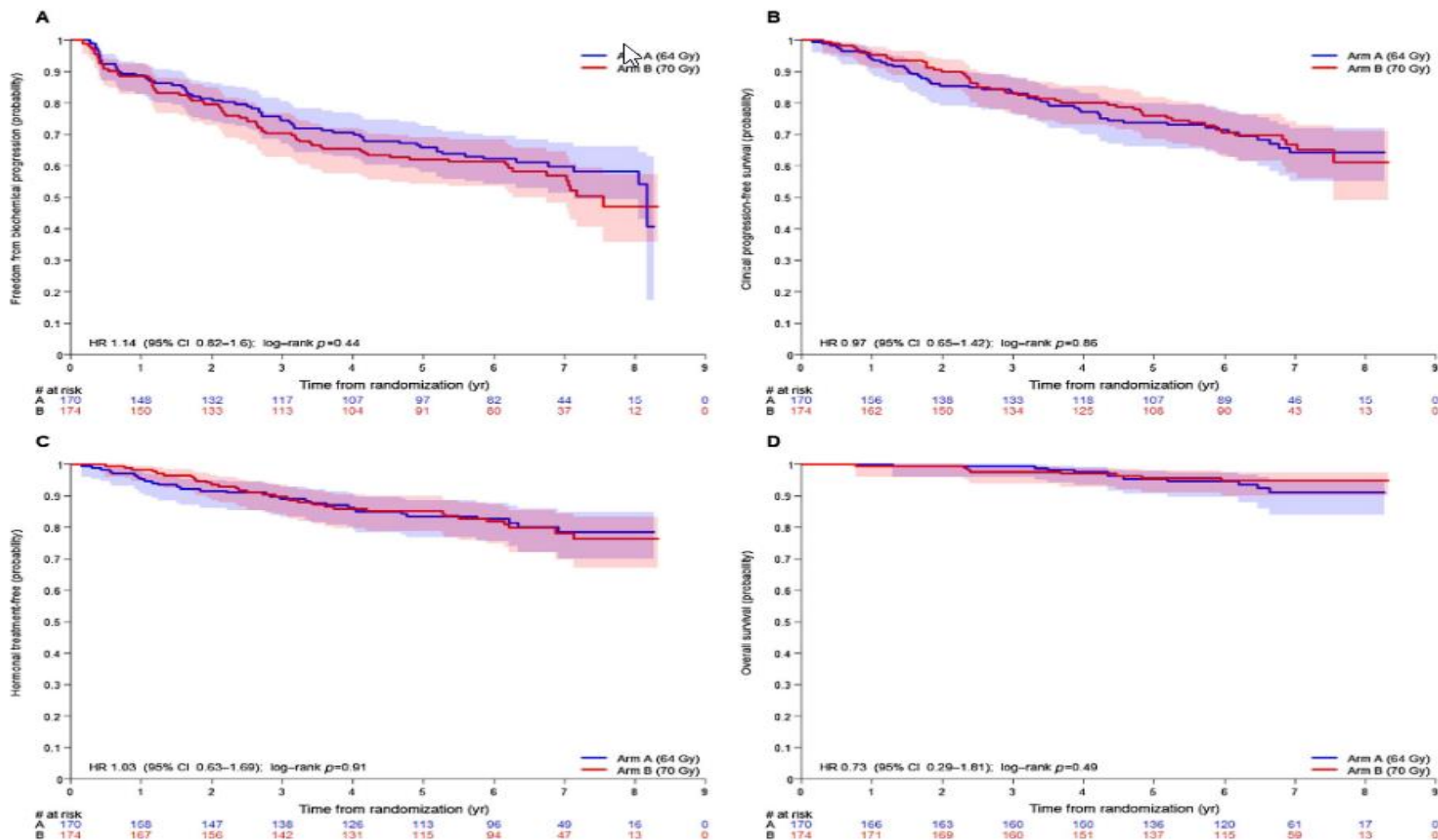


Fig. 2 – Kaplan-Meier analysis of (A) biochemical progression-free, (B) clinical progression-free, (C) hormonal treatment-free, and (D) overall survival. HR=hazard ratio; CI=confidence interval.

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ORIGINAL ARTICLE

Validation of the Decipher genomic classifier in patients receiving salvage radiotherapy without hormone therapy after radical prostatectomy — an ancillary study of the SAKK 09/10 randomized clinical trial[☆]

A. Dal Pra^{1,2*}, P. Ghadjar^{3,4}, S. Hayoz⁵, V. Y. T. Liu⁶, D. E. Spratt⁷, D. J. S. Thompson⁸, E. Davicioni⁶, H.-C. Huang⁶, X. Zhao⁶, Y. Liu⁶, C. Schär⁵, P. Gut⁹, L. Plasswilm^{2,10}, T. Hölscher¹¹, B. Polat¹², G. Hildebrandt¹³, A.-C. Müller¹⁴, A. Pollack¹, G. N. Thalmann¹⁵, D. Zwahlen⁴ & D. M. Aebbersold²

¹Department of Radiation Oncology, University of Miami Miller School of Medicine, Miami, USA; ²Department of Radiation Oncology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland; ³Charité — Universitätsmedizin Berlin, Berlin, Germany; ⁴Department of Radiation Oncology, Kantonsspital Winterthur, Winterthur; ⁵SAKK Coordinating Center, Bern, Switzerland; ⁶Decipher Biosciences (a subsidiary of Veracyte Inc.), San Diego; ⁷Department of Radiation Oncology, University Hospitals Seidman Cancer Center, Case Western Reserve University, Cleveland, USA; ⁸Emmes Canada, Vancouver, Canada; ⁹Kantonsspital Luzern, Luzern; ¹⁰Kantonsspital St. Gallen, St. Gallen, Switzerland; ¹¹Department of Radiotherapy and Radiation Oncology, Faculty of Medicine, Technische Universität Dresden, Dresden; ¹²Department of Radiation Oncology, University of Wuerzburg, Wuerzburg; ¹³University Hospital Rostock, Rostock; ¹⁴University Hospital Tübingen, Tübingen, Germany; ¹⁵Department of Urology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland



Available online 28 May 2022

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Single-dose carboplatin followed by involved-node radiotherapy for stage IIA and stage IIB seminoma (SAKK 01/10): a single-arm, multicentre, phase 2 trial



Alexandros Papachristofilou, Jens Bedke, Stefanie Hayoz, Ulrich Schratzenstaller, Miklos Pless, Marcus Hentrich, Susanne Krege, Anja Lorch, Daniel-M Aebbersold, Paul Martin Putora, Dominik-R Berthold, Deborah Zihler, Friedemann Zengerling, Annette Dieing, Arndt-Christian Mueller, Corinne Schaer, Christine Biaggi, Silke Gillessen, Richard Cathomas

Summary

Background Standard treatment options for patients with stage IIA or stage IIB seminoma include either para-aortic and pelvic radiotherapy or three to four cycles of cisplatin-based combination chemotherapy. These options result in 3-year progression free survival rates of at least 90%, but bear risks for acute and late toxic effects, including secondary malignancies. We tested a novel approach combining de-escalated chemotherapy with de-escalated involved node radiotherapy, with the aim of reducing toxicity while preserving efficacy.

Methods In the single-arm, multicentre, phase 2 SAKK 01/10 trial, patients with stage IIA or IIB classic seminoma (either at primary diagnosis or at relapse during active surveillance for stage I) were enrolled at ten centres of the Swiss Group for Clinical Cancer Research and ten centres of the German Testicular Cancer Study Group. WHO performance status 0–2, age 18 years or older, and adequate bone marrow and kidney function were required for eligibility. Treatment comprised one cycle of carboplatin (area under the curve 7) followed by involved-node radiotherapy (30 Gy in 15 fractions for stage IIA disease and 36 Gy in 18 fractions for stage IIB disease). The primary endpoint was 3-year progression-free survival. Efficacy analyses were done on the full analysis set, which comprised

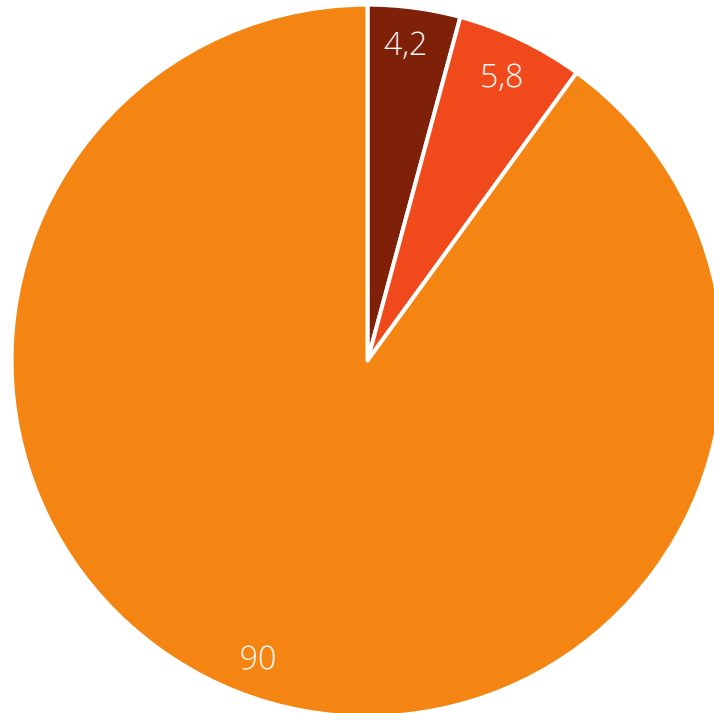
Lancet Oncol 2022; 23: 1441–50

Published Online
October 10, 2022
[https://doi.org/10.1016/S1470-2045\(22\)00564-2](https://doi.org/10.1016/S1470-2045(22)00564-2)

See [Comment](#) page 1349

Department of Radiation Oncology, University Hospital Basel, Basel, Switzerland (A Papachristofilou MD, U Schratzenstaller MD); Department of Urology (Prof J Bedke MD) and Department of Radiation Oncology (Prof A-C Mueller MD),

SAKK trial publication rate of 95.8%



■ Not Published ■ Published in other formats ■ Full Journal article

Of all SAKK trials closed between 1986 and 2021, 95.8% were published, 90.0% of them as full article, 5.8% in other formats.

Many Thanks to everybody who helped to achieve these excellent numbers!

Reference: Hayoz S, et al. BMJ Open 2023; doi:10.1136/bmjopen-2022-068490

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Thank You for Your Attention



 @MoShelan